

# Dietary interventions in irritable bowel syndrome

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|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>13/03/2015   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol |
| <b>Registration date</b><br>23/03/2015 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>07/04/2025       | <b>Condition category</b><br>Digestive System     | <input type="checkbox"/> Individual participant data                                              |

## Plain English summary of protocol

### Background and study aims

Irritable bowel syndrome (IBS) is a digestive disorder that affects up to 15% of the population. Symptoms include stomach pain, bloating and altered bowel habit. It can be very debilitating and has a great impact on the sufferers quality of life. A diet with an altered amount of carbohydrates (e.g. the types of fruits and vegetables) might prevent symptoms such as bloating, stomach pain and flatulence for many people with IBS. Recent research has shown that the diet described above can impact on the amount of bifidobacteria, a group of bacteria that live in the bowel. Prebiotics can promote (increase) the amount of friendly bifidobacteria in the bowel. This study will investigate the effect of this diet with a prebiotic food supplement on:

1. Bacteria in the bowel and the products of bacterial fermentation
2. Gut symptoms (e.g. wind, bloating)
3. Stool frequency and consistency
4. Changes to urine health markers in relation to the gut bacteria changes
5. Dietary intake
6. Quality of life

### Who can participate?

Patients of Guy's and St Thomas' NHS Foundation Trust or Barts and the London NHS Trust aged 18-65 years with IBS and without another major medical condition are eligible for this study

### What does the study involve?

Participants are randomly allocated into one of three groups. Those in group 1 are placed on a "sham" diet (one that is not expected to make a difference to the persons IBS symptoms) and are given a placebo pill to take for 4 weeks. Those in group 2 are placed on the treatment diet for 4 weeks and are given a placebo. Those in group 3 are also placed on the treatment diet and take the probiotic for 4 weeks. Each participant visits their study centre three times, once before the study begins, once at one week into the study period and once after the study ends. Participants are assessed according to, for example, what symptoms they experience, their nutrient uptake, quality of life and acceptability of the diet and food supplement.

### What are the possible benefits and risks of participating?

There are no anticipated risks to participants; however, changes to dietary intake will be

required for a 4-week period. Three stool samples and three urine samples will be collected and symptom, food and quality of life questionnaires will need to be completed. Routine dietary advice will be provided at the end of the study to all patients as per routine clinical care.

Where is the study run from?

King's College London and The Royal London Hospital (UK)

When is the study starting and how long is it expected to run for?

May 2015 to March 2017

Who is funding the study?

Study funding with research grant from Clasado (UK) ltd and departmental funding from King's College London Nutritional Sciences Division

Who is the main contact?

Bridgette Wilson

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## Contact information

### Type(s)

Public

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## Additional identifiers

# Study information

## Scientific Title

The impact of dietary interventions for irritable bowel syndrome on luminal microbiota, symptoms, nutrient intake and quality of life: a randomised controlled trial

## Study objectives

There is no difference in luminal bifidobacteria concentration between participants after four weeks of a sham diet versus four weeks of a treatment diet with added prebiotic.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Wales Research Ethics Committee 4, 30/04/2015, ref: 15/WA/0119

## Primary study design

Interventional

## Study design

4-week multicentre single-blind randomized three-armed parallel control trial

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Irritable bowel syndrome

## Interventions

1. 4 week sham diet + placebo
2. 4 week treatment diet + placebo
3. 4 week treatment diet + prebiotic

## Intervention Type

Supplement

## Primary outcome(s)

1. Luminal bifidobacteria concentration between groups at 4 weeks
2. Adequate symptom relief between groups at 4 weeks

## Key secondary outcome(s)

1. Difference in IBS symptoms between the three groups at 4-weeks.
2. Difference in stool consistency and stool frequency between three groups at 4-weeks
3. Difference in total and individual luminal gastrointestinal microbiota between the three groups at 4-weeks
4. Difference in faecal short chain fatty acids and pH between the three groups at 4-weeks
5. Differences in urine metabolomics between the three groups at 4-weeks
6. Difference in nutrient intake between dietary interventions at 4-weeks
7. Difference in QOL scores between the three groups at 4-weeks
8. Patient acceptability of the diet and food supplement (questionnaire)

**Completion date**

31/03/2017

## **Eligibility**

**Key inclusion criteria**

1. Men and women aged 18-65 years with diarrhoea-predominant IBS (IBS-D), mixed-type IBS (IBS-M) or unsubtyped IBS (IBS-U) based on Rome III criteria who do not have a major medical condition (diabetes, psychiatric or current eating disorders), gastrointestinal disease (e.g. inflammatory bowel disease, coeliac disease) or history of previous GI surgery, except cholecystectomy and haemorrhoidectomy
2. Individuals able to give informed consent
3. Individuals naive to the dietary intervention

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

65 Years

**Sex**

All

**Total final enrolment**

69

**Key exclusion criteria**

1. Females who report to be pregnant or lactating
2. Consumption of antibiotics, prebiotics or probiotics (in food products or as supplements) in the last 4 weeks prior to, or during the study
3. Use of unpermitted medications
4. Participants who have received bowel preparation for investigative procedures in the 4 weeks prior to the study
5. Participants who have had changes to IBS medications or dose in the 4 weeks prior to the study
6. Less than 2 days of at least moderate abdominal pain or discomfort in the screening week
7. Individuals with additional specific dietary needs
8. Individuals with excess alcohol or caffeine intake as assessed by diet questionnaires as these substances may confound symptom results

**Date of first enrolment**

04/05/2015

**Date of final enrolment**

09/09/2016

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Guy's and St Thomas' NHS Foundation Trust**

Westminster Bridge Road

London

United Kingdom

SE1 7EH

**Study participating centre**

**Barts and the London NHS Trust**

London

United Kingdom

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## **Sponsor information**

**Organisation**

King's College London

**Organisation**

Guy's and St Thomas' NHS Foundation Trust

**ROR**

<https://ror.org/00j161312>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Clasado (UK) Ltd

**Funder Name**

King's College London, Nutritional Sciences Division (UK)

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### Study outputs

| Output type                          | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>      | results | 01/06/2020   | 07/08/2020 | Yes            | No              |
| <a href="#">Results article</a>      |         | 14/06/2023   | 07/04/2025 | Yes            | No              |
| <a href="#">HRA research summary</a> |         |              | 28/06/2023 | No             | No              |